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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,062	04/30/2002	Thomas Moore	GK-OEH-120/500814.20021	7191
26418	7590	07/26/2004	EXAMINER	
REED SMITH, LLP			ALLEN, MARIANNE P	
ATTN: PATENT RECORDS DEPARTMENT			ART UNIT	PAPER NUMBER
599 LEXINGTON AVENUE, 29TH FLOOR				
NEW YORK, NY 10022-7650			1631	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.	MOORE ET AL.
Examiner	Art Unit Marianne P. Allen 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1) Responsive to communication(s) filed on 04 May 2004.  
2a) This action is FINAL.      2b) This action is non-final.  
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

4) Claim(s) 13-26 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) Claim(s) \_\_\_\_\_ is/are allowed.  
6) Claim(s) 13-26 is/are rejected.  
7) Claim(s) \_\_\_\_\_ is/are objected to.  
8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9) The specification is objected to by the Examiner.  
10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
    a) All    b) Some \* c) None of:  
        1. Certified copies of the priority documents have been received.  
        2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
        3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

1) Notice of References Cited (PTO-892)  
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
    Paper No(s)/Mail Date \_\_\_\_\_.  
4) Interview Summary (PTO-413)  
    Paper No(s)/Mail Date \_\_\_\_\_.  
5) Notice of Informal Patent Application (PTO-152)  
6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Abstract*

The corrected abstract submitted 5/4/04 is noted. However, this abstract contains errors. While it now includes  $\tau$ , it no longer reflects the subscripting for  $m_1$ ,  $m_2$ ,  $m_n$ , etc. Correction is requested.

### *Specification*

The statement with respect to the substitute specification filed on 1/4/02 containing no new matter on page 9 of the response submitted 5/4/04 is noted. The marked up copy of the substitute specification filed 1/4/02 has been located. As such, the substitute specification filed 1/4/02 has now been marked for entry.

The amendment filed 5/4/04 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant has requested insertion of multiple paragraphs at page 9 of the specification. Basis is stated to be in the claims or elsewhere in the originally filed specification. The seventh paragraph recites “after at least one separation step.” Basis for this is not seen in the claims. The twelfth paragraph recites “said analysis data being associated with said M liquid fractions.” Basis for this is not seen in the claims or elsewhere in the originally filed specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 112***

Claims 19 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 19 and 24 are not original claims and no basis has been pointed to in support of these new claims other than the originally filed claims. However, at least the limitation “after at least one separation step” in claim 19 and “said analysis data being associated with said M liquid fractions” does not appear in the original claims.

Claims 13-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compilation of data for M liquid fractions (such as in a table), does not reasonably provide enablement for combining analysis data in any other ways. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In response to the enablement rejection set forth in the prior Office action, applicant has responded by indicating that the intent of the method is to gather the data from the M liquid fractions. That is, the information is not combined so much as all of the data results are compiled or put together. However, the claims are not considered to be so limited. “Combining the analysis data” is considered to imply some algorithmic or more sophisticated analysis than merely compilation of data. The benefits and/or comparisons between different proteomes

argued by applicant on page 12 of the response are not considered to be clearly set forth in the claim nor enabled.

Applicant has argued that the number of liquid fractions required or desirable for each step is dependent upon the sample used with respect to the number and characteristics of the proteins and the character and quality of separation. However, the specification gives no such guidance as to how or on what basis to make these selections. The claims do not require or guide one to separations where most or all of the fractions contain protein (i.e. to avoid empty fractions) or collecting ~~whole~~ peaks in the fraction.

Claims 13-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is confusing in requiring that  $M$  liquid fractions are identified by  $\tau$  different analysis processes qualitatively yet never using this qualitative data in any way. That is, as amended the claim appears to only use the quantitative determination of the  $M$  liquid fractions by known quantification processes. If the qualitative information is intended to be used in some way in the “combining the analysis data” step, this is unclear. It is further unclear if the identification of  $M$  liquid fractions by  $\tau$  different quantitative processes as set forth in lines 9-10 is a repetition of the determining said liquid fractions quantitatively by known quantification processes as set forth in lines 10-11. That is, are these two portions of the claim referring to the same quantitation of the liquid fractions or are two separate quantitations of the liquid fractions taking place?

Claim 14 remains confusing in reciting “according to the affinity of the protein, with respect to specific ligands, also to antibodies.” This phrase is confusing as to what was intended. Note that the processes listed are not listed in the alternative (i.e. “a, b, or c”) in the claim as amended.

Claim 16 remains confusing in reciting “selected as quantification processes.” It is unclear if this refers to the quantification in line 10 or line 11 (or both) of claim 13.

Claim 19 now recites a “two-dimensional multiple vessel system with the layout of microtitration plates.” Likewise, claims 20-21 recite “in a defined grid” and new claims 25-26 recite “n \* 96 grid of microtitration technology.” It appears that conventional and well-known multiple well plates (i.e. 96 well microtiter plates) were intended. However, the language in the claims does not appear to be conventional or routinely used language for this concept. As such, the claims are unclear as to what was intended. Furthermore, it must be assumed that the “n” in claims 25 and 26 do not correspond to the “n” different separating processes in claim 13.

Claim 24 remains unclear in reciting “wherein the analysis data...are assembled in a database.” The claim does not make clear what specific pieces of information are required to be present in the database in order to meet the limitation of the claim. Does this mean only the final n-dimensional data space representation? Does it include the number of liquid fractions? Does it include identifiers and quantifiers? Applicant’s amendment to the claim does not address this.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-14, 16-19, 21, and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Opiteck et al. (Analytical Biochemistry, May 1998).

Opiteck et al. discloses a method for multidimensional analysis of a proteome. The proteome is first separated according to size using size exclusion chromatography (SEC). In a second step the protein fractions obtained thereby are concentrated on an RP-HPLC column and separated from the elution liquid used for the SEC method. Next, the concentrated protein fractions are separated according to their hydrophobicity using a gradient elution. The liquid fractions are quantitatively measured using UV-spectroscopy and the proteins obtained therefrom are identified by means of MALDO-TOF/MS, ESI/MS or sequencing. Following at least one separation step the fractions were deposited into 96-well microtiter plates. The compilation of the information meets the limitation of an n-dimensional image of the proteome and the saved data with respect to the proteome meets the limitation of a database as set forth in claim 24. See abstract and figures.

Claims 13-18 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Blackstone et al. (TIBTECH, March 1999).

Blackstone et al. discloses multidimensional analysis of a proteome comprising affinity separation followed by 2D gel electrophoresis. Identification of proteins is by mass spectrometry. Information about the proteome is saved. See at least abstract and figures.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 571-272-0712. The examiner can normally be reached on Monday-Thursday, 5:30 am - 1:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-0722. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete

service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

*Marianne P. Allen*

Marianne P. Allen  
Primary Examiner  
Art Unit 1631

7/22/04

mpa